

Guidelines for Submitting Samples to NQCL

A step-by-step guide for clients submitting samples for testing





Sample Submission Requirements

Original Packaging

Samples must be in original, untampered packaging with proper sealing and labeling

Temperature Control

Samples requiring storage below ambient temperature must be delivered in appropriate temperature-controlled containers

Analysis Request Form

All samples must be accompanied by a properly filled Analysis Request Form (available at the Laboratory or downloadable from www.nqcl.go.ke)

Required Information on Analysis Request Form

Name and address of applicant

Sample size and pack information

Company contact information

Reference number and storage conditions

Product name and presentation

Tests requested and method of analysis

Manufacturer details

List of accompanying items (e.g., working standards)

Sample information (batch number, manufacture date, expiry date, active ingredients)

Authorizing person's details (name, signature, designation, contact information)

Incomplete forms may result in sample rejection or delayed analysis

Sample Size Requirements

The minimum number of samples required depends on formulation type and pack size:

Tablets & Capsules

All pack sizes: 100 tablets/capsules

Suspensions & Syrups

<10 mL: 50 bottles

10-900 mL: 20 bottles

1000-2000 mL: 10 bottles

>2000 mL: 4 bottles

Injectables

<10 mL: 100 vials/ampoules

10-100 mL: 50
vials/ampoules/bottles

110-2000 mL: 10 bottles

>2000 mL: 6 bottles

Sample size for other formulations available upon request

Special Sample Requirements



Registration Samples

Must have at least one year of shelf life remaining at time of receipt

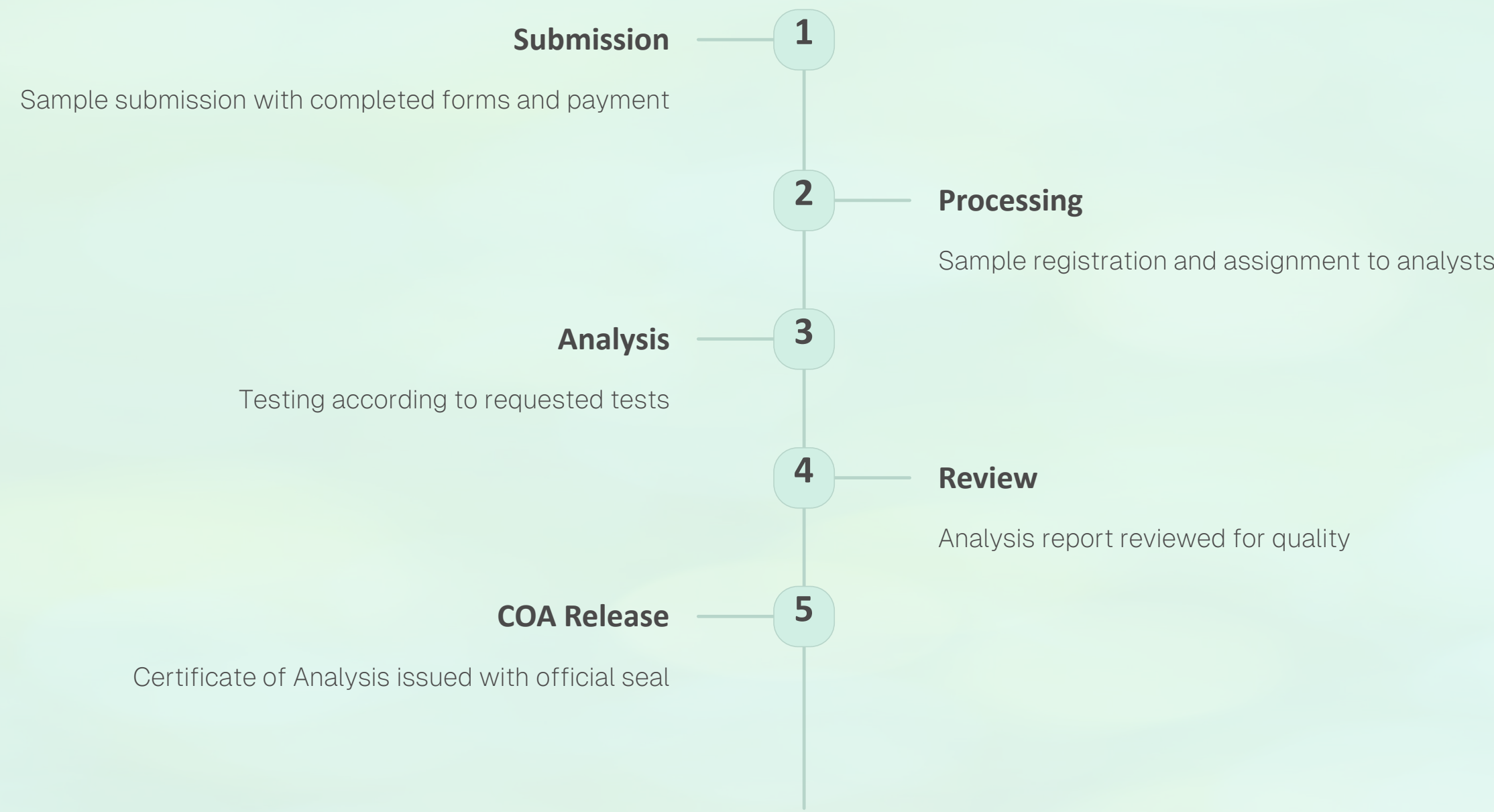
Non-Pharmacopoeial Samples

Must include manufacturer's methods, specifications, and validation data

Reference Standards

200 mg - 1.0 g with valid certificates of analysis and at least 6 months shelf life

Laboratory Analysis Timeline



Note: Analysis duration may vary depending on sample complexity



Payment and Reports

Payment Process

- Private clients receive a proforma invoice/quotation
- Full payment required during or before sample submission
- Payments accepted via banker's cheque or company cheque
- All payments made payable to "NATIONAL QUALITY CONTROL LABORATORY"
- Refund requests handled through Laboratory's Accounts office

Analysis Reports

- Results provided as official Certificate of Analysis (COA)
- Each batch receives its own COA
- Only one COA issued per sample
- Certified copies available at Ksh. 1,000 per copy upon written request
- Detailed reports available for additional fee

Important Policies



Confidentiality

No client is allowed to communicate directly with any analyst



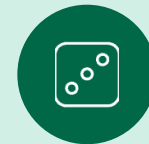
Complaints

Contact Quality Assurance Unit for guidance on reporting and handling complaints



Appeals

Requests for re-analysis must be submitted in writing within 30 days of receiving COA



Expired Samples

Laboratory will notify client if sample expires before analysis completion

The Laboratory reserves the right to accept or reject samples if conditions are not met

Sample Transportation Responsibility

Client Responsibility

It is the client's responsibility to ensure safe transport of samples to the Laboratory unless specifically arranged otherwise

For special transport arrangements:

- Submit request in writing
- Client bears the cost of transport
- Samples requiring thermal preservation must be transported on ice and remain cool until receipt

